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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,333	01/27/2006	Gilad Lavi	S2082/20004	4212

3000 7590 06/23/2009

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EXAMINER	
ANDERSON, MICHAEL J	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
06/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No.	Applicant(s)	
	10/566,333	LAVI ET AL.	
	Examiner	Art Unit	
	MICHAEL J. ANDERSON	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/7/2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-25, 38-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22-25, 38-43 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the "driver" of claim 9 and the "rod" of claims 22-25. Claims 38-43 call for a "driver" and a "rod" however, the driver and rod appear to be the same element (at least 371).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1--31, 35-36, 44-66, 69 and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by McWethy (US 2003/0229314).

With regards to claims 1, 9, 44 and 45, McWethy discloses (figure 1-21) an injection device comprising: a housing (50) having a proximate end (near 52) and a distal end, the distal end (near 51) having an opening therein; a shield (20) slideably coupled to the housing and having a shield base (21) and aperture (33) positioned at said distal end thereof; a cartridge barrel (30) within the housing, the cartridge barrel having proximate and distal ends; a needle cannula (12) fixed to the distal end of the cartridge barrel, or attachment means for fixing a needle cannula to the distal end, said needle cannula being disposed within said shield prior to activation of said device; a stopper (38) within the cartridge barrel; a driver (42) coupled to the stopper; a spring (24) coupled between the housing and the driver; an automatic driver trigger (46, figures 5 and 6) for retaining the driver fixed to the housing and in which state the spring is in a compressed state, the trigger being actuable by displacing said shield towards said proximal end of housing, thereby permitting passage of said needle cannula through

said aperture, said actuated trigger automatically releasing the driver from the housing thereby allowing the spring to urge the driver through the housing and with it the stopper through the cartridge barrel; and a release mechanism (26) for releasing the spring from the driver at some point on its travel through the housing, whereupon the spring engages the shield base and automatically urges the shield away from the housing so as to cover the needle cannula.

With regards to claim 2, McWethy discloses (figure 1-21) an injection device according to claim 1 and comprising means for allowing the driver to drive the cartridge barrel through the housing following activation of said driver trigger and prior to movement of the stopper through the cartridge barrel, thereby urging the needle cannula outward relative to the housing and shield (figures 4, 9 and 12).

With regards to claim 3, McWethy discloses (figure 1-21) an injection device according to claim 1, the driver trigger being coupled to said shield, wherein movement of the shield inwardly with respect to the housing activates the trigger (figures 5 and 6).

With regards to claim 4, McWethy discloses (figure 1-21) an injection device according to claim 3, wherein said trigger is actuated prior to the emergence of the needle cannula from the shield (figure 10).

With regards to claim 5, McWethy discloses (figure 1-21) an injection device according to claim 3, wherein said trigger is actuated subsequent to emergence of the needle cannula from the shield (figure 6).

With regards to claim 6, McWethy discloses (figure 1-21) an injection device according to claim 1, wherein the driver trigger (46) comprises a resilient member on

one of the driver and the housing and a complimentary engaging member on the other of the driver and housing, and wherein said trigger is actuated by a force of sufficient magnitude applied between the driver and the housing (figures 5 and 6).

With regards to claim 7, McWethy discloses (figure 1-21) an injection device according to claim 1, wherein said driver trigger (46) comprises a resilient member on one of the driver and the housing and a complimentary engaging member on the other of the driver and housing, and wherein said trigger is arranged to receive a trigger release member (26) of the shield following movement of the shield into the housing.

With regards to claim 8, McWethy discloses (figure 1-21) an injection device according to claim 1, wherein said housing is generally cylindrical in shape and the spring and cartridge barrel are located coaxially within the housing.

With regards to claim 10, McWethy discloses (figure 1-21) the automatic injector of claim 9, wherein said shield displacement and driver disengagement require a substantial force (pp[0038]) over a short travel distance.

With regards to claim 11, McWethy discloses (figure 1-21) the automatic injector of claim 10, wherein said shield displacement and driver disengagement force required from the user is about 1 kgf.

With regards to claim 12, McWethy discloses (figure 1-21) the automatic injector of claim 10, wherein the driver disengagement from the housing takes place over the initial part of the shield travel.

With regards to claim 13, McWethy discloses (figure 1-21) the automatic injector of claim 9 wherein said force exerted by the automatic injector on the shield is minimal during delivery.

With regards to claim 14, McWethy discloses (figure 1-21) the automatic injector of claim 9, further comprising an automatic retracting mechanism that automatically retracts said shield after the completion of injection (figures 5 and 6, pp[0047]).

With regards to claim 15, McWethy discloses (figure 1-21) the automatic injector of claim 14, wherein said driver is arranged to allow the driving unit to force the retraction of the shield and shielding the needle at the end of delivery.

With regards to claim 16, McWethy discloses (figure 1-21) the automatic injector of claim 9 wherein said housing includes a set of supports (57, 150, 230) extending longitudinally from a proximate end of the housing, said supports adapted to abut said cartridge and prevent axial movement of said cartridge before, during and after operation of the automatic injector.

With regards to claim 17, McWethy discloses (figure 1-21) the automatic injector of claim 9, wherein said driver includes a set of cartridge barrel supports extending longitudinally and which slide on the external surface of the barrel during injection.

With regards to claim 18, McWethy discloses (figure 1-21) the automatic injector of claim 17, wherein said cartridge barrel supports are adapted to detect the end of barrel and release the driving unit.

With regards to claim 19, McWethy discloses (figure 1-21) the automatic injector of claim 9 wherein said driving unit is a spring (24) arranged to bias said driver to push said stopper into said barrel and then move said shield into a needle shielding position.

With regards to claim 20, McWethy discloses (figure 1-21) the automatic injector of claim 19, wherein the released spring provides the user with a tactile and audible feedback of the end of delivery (inherent during operation of the device).

With regards to claim 21, McWethy discloses (figure 1-21) the automatic injector of claim 9 wherein said driver comprises protrusions (46) that releasably engage said housing.

With regards to claim 22-25, McWethy discloses (figure 1-21) the automatic injector of claim 9 wherein said housing has an opening at said proximate end, said injector further comprising a rod (42, same a driver) extending through said opening and arranged to push said stopper into said barrel before activation of said injector.

With regards to claim 26, McWethy discloses (figure 1-21) the automatic injector of claim 9 further comprising a safety tab (360, 362) removably engaged with said enclosure, said tab arranged to prevent activation of said injector when said tab is engaged with said enclosure.

With regards to claim 27, McWethy discloses (figure 1-21) the automatic injector of claim 9 wherein said cartridge has a closed distal end (36) and a proximate end, said needle having a distal end for exposure to the injection site and a proximate end arranged to penetrate said closed distal end of the cartridge and providing fluid

communication between the distal end of the needle and the interior of the cartridge, said proximate end of said cartridge arranged to accept said driver.

With regards to claim 28, McWethy discloses (figure 1-21) the automatic injector of claim 9 wherein said shield has an inner circumferential wall and an outer circumferential wall, said housing having an inner circumferential wall and an outer circumferential wall, said housing and said shield arranged in a sliding relationship, said housing and said automatic injector having an arrangement for latching the shield in the needle shielding position.

With regards to claim 29, McWethy discloses (figure 1-21) the automatic injector of claim 28, wherein said enclosure further comprises a leaf spring (360, 362) at said distal end of the enclosure, said leaf spring arranged to abut said driving unit after retraction of said shield and prevent potential re-exposure of said needle.

With regards to claim 30, McWethy discloses (figure 1-21) the automatic injector of claim 28, wherein said enclosure further comprises pins and pattern arranged at said distal end of enclosure, said pins and pattern arranged to interact during the use of the automatic injector and prevent potential re-exposure of said needle.

With regards to claim 31, McWethy discloses (figure 1-21) the automatic injector of claim 21, wherein said activation of said injector occurs after application of the axial pressure on the housing of the injector; said shield moving to expose the needle and to separate said protrusions from said housing to allow axial movement of said driver and said stopper in said barrel, holding said injector at the injection site for the during of the injection.

With regards to claim 35, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 28, wherein said shield outer circumferential wall are arranged in a sliding relationship with said housing inner circumferential wall.

With regards to claim 36, McWethy discloses (figure 1-21) the automatic injector of claim 28, wherein said shield inner circumferential wall are arranged in a sliding relationship with said housing outer circumferential wall.

With regards to claim 46, McWethy discloses (figure 1-21) the automatic injector of claim 45, wherein said shield displacement requires a substantial force over a short travel distance.

With regards to claim 47, McWethy discloses (figure 1-21) the automatic injector of claim 46, wherein the shield displacement force is sufficient to ensure rapid housing and shield disengagement.

With regards to claim 48, McWethy discloses (figure 1-21) the automatic injector of claim 45, wherein said the force exerted by the shield of the automatic injector on the tissue is minimal during delivery.

With regards to claim 49, McWethy discloses (figure 1-21) the automatic injector of claim 48, wherein the shield and the housing have latches maintaining the relative housing to shield position during delivery.

With regards to claim 50, McWethy discloses (figure 1-21) the automatic injector of claim 45, wherein the force exerted by the automatic injector moves the cartridge toward the distal end of the automatic injector to insert the needle into tissue and deliver the drug.

With regards to claim 51, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 45, further comprising a mechanism that automatically retracts said shield and shields the needle after the completion of injection

With regards to claim 52, McWethy discloses (figure 1-21) the automatic injector of claim 51, wherein said driver is arranged to allow the driving unit to force the shield in the distal direction and shield the needle at the end of delivery.

With regards to claim 53, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 45, wherein said housing includes a support extending longitudinally from said proximate end of the housing, said support adapted to abut said cartridge barrel and prevent axial movement of said cartridge before use.

With regards to claim 54, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 45, wherein said shield includes protrusions extending longitudinally from the distal end and limiting cartridge motion toward the distal end of the injector after activation.

With regards to claim 55, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 45, wherein said driver includes a set of barrel supports extending longitudinally and sliding on the external surface of the barrel during injection.

With regards to claim 56, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 55, wherein said cartridge barrel supports are adapted to detect the end of barrel and release the shield.

With regards to claim 57, McWethy discloses (figure 1-21, as for the above claims) the

automatic injector of claim 55, wherein said driver has protrusions supporting the barrel from axial motion toward the distal end of the automatic injector after injection completion.

With regards to claim 58, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 45, wherein said driving unit is a spring arranged to bias said driver to push said cartridge to insert the needle into tissue, to push said stopper into said barrel and then move said shield into needle shielding position.

With regards to claim 59, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 58, wherein said released spring provides the user with a tactile and audible feedback of the end of delivery.

With regards to claim 60, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 45, wherein said driver comprises protrusions, said driver protrusions releasably engaging said housing.

With regards to claim 61, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 60, said activation of said injector occurs after application of an axial force on the shield of the injector; said shield moving to separate said driver protrusions from said housing to allow fluid delivery while holding said injector at the injection site for the duration of the injection.

With regards to claim 62, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 45, wherein said cartridge comprises a barrel having a closed distal end and a proximate end, said needle having a distal end for exposure to the injection site and a proximate end arranged to penetrate said closed

distal end of the cartridge and provide fluid communication between the distal end of the needle and the interior of the cartridge, said proximate end of said cartridge arranged to accept said driver.

With regards to claim 63, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 45, wherein said shield has an inner circumferential wall and an outer circumferential wall, said housing having an inner circumferential wall and an outer circumferential wall, said housing and said shield arranged in a sliding relationship, and said automatic injector having arrangements for latching the shield to the housing.

With regards to claim 64, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 63, wherein said shield further comprises a hook at said distal end and the housing comprising matching windows at distal end of said housing for engaging the shield and housing in storage and delivery positions.

With regards to claim 65, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 63, wherein said shield further comprises a leaf spring said leaf spring arranged to abut said driving unit after retraction of said shield and prevent potential re-exposure of said needle.

With regards to claim 66, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 45, further comprising a safety tab remove- ably engaged with said enclosure, said tab arranged to prevent activation of said injector when said tab is engaged with said enclosure.

With regards to claim 69, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 45, wherein said injector is equipped with a safety tab said shield proximate displacement requires the removal of the safety tab.

With regards to claim 70, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 45, wherein said injector is equipped with a needle cover assembly cup (13), said shield displacement requires the removal of the cup together with the needle cover assembly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-34, 37, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over McWethy in view of Gabriel (US 5,114,406).

With regards to claim 32-34, 37, 67 and 68, McWethy discloses (figure 1-21, as for the above claims) the automatic injector of claim 28, 32 and 63. However McWethy does not disclose wherein said housing and shield further include a window arranged to allow viewing of the barrel, a barrel scale and the fluid in the barrel. Gabriel discloses a viewing window (33). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the device of McWethy as disclosed by Gabriel for view the contents of the cartridge.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18, 1-24 of copending Applications No. 10, 566,226 and 11/666851, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both applications claim similar if not identical subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Amendment

The present communication responds to the Amendment of 3/6/2009. By this communication, claims 1, 9, 16, 27, 38, 44-45, 53, 55 and 62 were amended. The amendments did not add new matter. Claims 1-70 are pending. The rejection(s) are as stated.

Response to Arguments

Applicant's arguments with respect to claims 1-70 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ANDERSON whose telephone number is (571)272-2764. The examiner can normally be reached on M-F 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael J Anderson/
Examiner
Art Unit 3767

MJA
6/19/2009
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767